REMARKS

Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow. This amendment is submitted in reply to the Final Office Action mailed July 21, 2010 ("the Action"). Claims 1-13, 15-23, 24 and 41-57 are pending in the application.

The Action continues to reject the claims as allegedly being obvious over US 2002/0193685 to Mate ("Mate") in view of U.S. 4,945,914 to Allen ("Allen"), and for some of the dependent claims, in further view of WO/97/33513 to Knapp (Knapp).

A. The Claims are Patentable over Mate and Allen

The Action concedes that Mate does not teach a mechanism configured to controllably move the solenoid and a controller which directs the movement of the mechanism, but alleges that Mate does disclose generating a coupling signal (citing para. 35 and 37-39, and movable gantry element 20). Action, p. 8. Applicant is unsure how the moveable gantry 20 relates to the tracking/location signal of the sensor array 34 of Mate. In any event, the Action further states that Allen teaches the articulating arm mechanism and sensor features (citing to col. 15, lines 12-27) and alleges that one of skill in the art would have found it obvious to modify Mate to include a mechanism to control movement of the solenoid per Allen "because with the robot mechanical arm and sensor/solenoid at its tip [the] surgeon can effectively keep track of the solenoid/fiducial implant inside the body." (Action, p. 3, p. 8). Applicant respectfully disagrees.

Applicant agrees that Mate proposes a Guided Radiation Therapy System. Mate proposes using markers 30 that are energized by an excitation source 32 and an array of sensors 36 positioned in a fixed selected geometry relative to each other so that the array 34 defines a fixed reference coordinate system from which location and movement are calculated. Para. 48. Each marker resonates at a selected unique frequency and generates a low energy RF magnetic signal measurable from outside the body. The signals from the markers are detected and measured by the array 34 of sensors 36 located outside the body. The measurement information from each sensor as determined by the fixed array of sensors

determines the location of the markers 30 relative to the sensors (Para. 36).

Mate states that "the position of each sensor 36 on the frame 70 is fixed and defines fixed reference points for obtaining measurement data used by the computer controller 38." (Para. 48). Mate goes on to state that the "sensor array 34 provides the *fixed* reference structure from which measurements are taken and calculations performed to determine the relative positions of the target 12, the target isocenter 40 and the machine isocenter 22." (emphasis added, Para. 48) Also, Mate states that the sensor array 34 can be placed on, under or connected to the support table 76 or mounted to the gantry so that the position of the machine isocenter relative to the sensor array 34 is known. (Para. 57, Figure 10). Thus, and noably, Mate proposes an array of external sensors that are static relative to each other and cannot move in a 3-D pattern in free space. *See, e.g.*, Figure 10.

Applicant respectfully submits that Mate *teaches away* from using an external solenoid that is moveable in a three-dimensional pattern in free space outside the patient.

Page 16 of the pending application states:

> The positional data and associated coupling signal strength can be analyzed to define a unique trajectory that establishes the maximal signal strength. The maximal value of the signal itself may not be important, as the relative maximal value is used to define the spatial location of the sensor unit. Nonetheless, if the maximal value is significantly different from an *a priori* or predicted value, an error or alert as to the presence of a potential abnormality may be noted to allow a clinician to take remedial actions (such as to reinitiate the operations). The unique trajectory can be used to define at least one of spatial position and/or orientation. In certain embodiments, the arm **60** translates the solenoid through a controlled three-dimensional travel path while the coupling signal strength **20s** is monitored.

Applicant agrees that Allen describes the use of a robot arm 34 with a base 36 defining the origin (0, 0, 0) of the external coordinate system B. At the tip 38 of the robot arm 34 is a sensor 40. The sensor 40 can be a metal detector or an ultrasonic detector (or any instrument) that can sense the position of a fiducial implant 10 in a body 32 (col. 15, lines 11-20). The arm has sensors at joints and the system can track the arm so that the tip location of the arm is always known (col. 15, lines 27-34). Applicant submits that Allen does not

electrically couple a solenoid on the robotic arm with a solenoid of the fiducial implant(s) to provide ***a coupling signal*** that is used to determine the position of the implants at all. Indeed, Allen uses images and scan planes and correlates internal and external coordinates systems. While Allen describes that the arm 34 is tracked, it does so based on the location of the tip of the arm. The fiducial implants are used to define an internal coordinate system and are not coupled to the arm sensor 40. The arm sensor 40 and implants do not cooperate, much less use external and internal solenoids, to generate a coupling signal that is used to determine the location of the implant. Allen states:

> When the tip 38 of the arm 34 rests on implant 10 in the skull 18, the location of the internal coordinates system A defined by fiducial implants 10 is known with respect to the external coordinate system B. Supplying the Euler angels of rotation and the location of the tumor which is known relative to the internal coordinates system A to the computer, provides the ability to determine the location of the tumor in the external coordinate system B.

(Allen, col. 15, lines 33-43). Thus, even combined, the cited prior art fails to teach or suggest the claimed coupling signal subject matter.

Further, Mate and Allen work in very different ways. Applicant submits that one of skill in the art would not have modified Mate to use the arm of Allen, much less in the manner alleged by the Action, as each works as intended and there is simply no motivation to combine these references in the manner alleged absent the teachings of the pending application.

Notably, despite the fact that Allen issued in 1990, more than 10 years *before* the filing date of Mate, Mate fails to teach or suggest the use of a moving arm/mechanism with an external solenoid that couples to the internal solenoid to identify position of the internal sensor/marker. Indeed, the fixed array of sensors of Mate *teaches away* from the use of the movable arm.

In response to Applicant's prior arguments with respect to the deficiencies and/or improper combination of Mate/Allen, the Action states that Allen is relied on only for teaching a robot arm and a sensor/solenoid at its tip and that Mate is cited for teaching a coupling signal between the external and internal solenoid (citing para. 35, 37-39, movable

gantry element 20). Action, p. 7-8. The Action states that when current is passing through the solenoid a magnetic field is created. The Action then alleges that when a solenoid moves or rotates, the signal strength and shape changes. While this may be true, as discussed above, Mate teaches away from the use of an external solenoid moveable in a three-dimensional pattern to generate the coupling signal and determine location of the internal solenoid/sensor as recited in the independent claims.

Applicant submits that it is improper to take isolated features from different prior art references without considering the overall teachings of the reference itself. Allen teaches a very different system from that proposed by Mate, and Mate's configuration provides its own tracking and locating methodology. There is no indication that modifying Mate as alleged would provide an improved tracking/locating as alleged by the Action to be the "motivation" for such modification (Action, p. 8). Thus, the Action's alleged motivation to modify Mate to use the articulating arm of Allen is deficient and appears to be based on improper hindsight. Applicant submits that there is no such motivation, as Mate identifies its target location and controls the machine isocenter location using a fixed sensor array. The use of an external solenoid that can move in a three-dimensional pattern which would appear to be a more complex way of providing the machine isocenter information.

Applicant respectfully submits that the test for patentability is not whether isolated elements of the claimed subject matter exist in different prior art references. Indeed, as noted by the U.S. Supreme Court in *KSR International Co. v. Teleflex Inc., et al.*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art (550 U.S. 1, 14 (2007)). The unwitting use of hindsight is inappropriate.

In, *Ex parte So and Thomas*, the Board of Patent Appeals and Interferences (BPAI) reversed the Examiner for rejecting the claims using the unwitting application of hindsight. In *Ex parte So and Thomas*, the BPAI stated that there is nothing in the applied references that would have motivated an artisan to select the particularly claimed ingredients and use the resulting composition as claimed. *Ex part So and Thomas*, BPAI 2007-3967 (January 4, 2008) at 5. Here, the analogy can be made that there is nothing in the cited art that would

have motivated an artisan to use the articulating arm of Allen with the fixed array system of Mate, particularly when each reference operates in a very different manner and, indeed, Mate *teaches away* from the use of an external solenoid that is movable in a three-dimensional pattern in free space as recited in independent Claims 1, 23 and 34. Applicant submits that the claims are patentable for at least this subject matter.

B. Claim 18

Mate requires a fixed array of external sensors to detect the marker position in the patient. Applicant has amended Claim 18 to recite that the external solenoid is **a single** solenoid that resides on an end portion of the articulating arm. Applicant submits that Mate clearly teaches away from such a configuration. Allen touches the fiducial marker and operates in a different manner. Applicant submits that Claim 18 is patentable over the cited prior art.

C. Claims 15, 16 and 48

The Action alleges that the "combined" Mate and Allen system performs the functions of Claims 15, 16 and 48 "because the system has to evaluate signal shape and strength coming from internal sensor in order to locate the internal sensor position." Action, p. 4. Moreover, the Action states that Allen proposes moving a robot arm through three-dimensional space to determine the position of the sensor inside the body to find the implant. While this may be true, the 3-D movement of the robot arm does not generate a coupling signal that is used to determine the location of the implant.

Rather, as discussed above, Mate uses a fixed sensor array and Allen uses a mechanical arm with a sensor on its tip; neither uses an external solenoid that generates a coupling signal shape, much less one that is deconvoluted to determine the location of the implant as recited in Claims 15, 16 and 48.

> 15. A system according to Claim 1, wherein the external solenoid generates a coupling signal shape that varies with spatial and angular orientation with the internal solenoid of the sensor unit, and wherein said

computer module evaluates the detected coupling signal strength and shape and deconvolutes the coupling signal with respect to position to determine the spatial location of the sensor in the subject.

16. A system according to Claim 15, wherein the controller directs the mechanism to move the solenoid through the three dimensional pattern in free space to generate the coupling signal, and wherein the computer module that evaluates the coupling signal strength uses the deconvoluted coupling signal to determine the position of the sensor unit.

48. A system according to Claim 1, wherein the external solenoid generates a coupling signal shape that varies with spatial and angular orientation with the internal solenoid of the sensor unit, and wherein said computer module comprises non-transitory computer readable storage medium with computer program code that deconvolutes the signal shape with respect to position to determine the spatial location of the sensor in the subject.

Again, Applicant submits that clearly Allen does not teach or suggest moving the mechanism arm through a 3-D pattern in free space to generate the coupling signal. Rather, Allen proposes **contacting** the tip sensor to the fiducial marker. Applicant submits that Claims 15, 16 and 48 are patentable over the cited prior art.

D. Claims 23 and 41

The Action alleges that Mate tracks the position of the marker and selectively applies radiation to the target. While this may be true, the marker of Mate is simply a marker; it is not a sensor nor does it sense an internal parameter, much less detect radiation internally.

23. A method of obtaining spatial data and radiation dose data regarding a target *in vivo* treatment site, comprising:

sensing *in vivo* at least one predetermined parameter of interest in a patient using at least one implanted sensor unit;

wirelessly transmitting data associated with the sensed at least one parameter from the at least one sensor unit to an external reader;

moving an articulating arm about the patient in a three-dimensional pattern in free space outside the patient, the articulating arm having an associated coupling member located external of the patient proximate the target treatment site, the coupling member being configured to cooperate with

the at least one implanted sensor to generate a coupling signal with a signal strength that varies in relation to the position of the coupling member with respect to the at least one sensor unit;

detecting the signal strength of the coupling signal at a plurality of locations traveled based on the moving step; and

determining the position of the at least one sensor unit in the body based on the detecting step, thereby having the implanted sensor unit act as a positional marker and an *in vivo* sensor.

41. A method according to Claim 23, wherein the at least one sensor unit is a plurality of sensor units, wherein the target treatment site is associated with cancerous tissue, and wherein the at least one parameter comprises radiation and the method comprises determining the radiation dose delivered to the target site based on the sensing and transmitting steps.

These claims are patentable for at least the features emphasized above.

E. Claims 2, 17 and 50

The Action alleges that Mate somehow renders the subject matter of Claims 2, 17 and 50 obvious but never discusses these claims particularly (Action, para. 2, and para. 4, p. 3). Rather, these claims are grouped with other claims as a single rejection. Applicant submits that this is an improper ground of rejection for at least Claims 2, 17 and 50.

Claim 2 and 50 are directed at sensing at least one internal parameter using the implantable unit as a sensor and Claim 17 is directed to evaluating whether there is an angular shift from an a prior position. Applicant respectfully submits that these claims are patentable over the cited prior art. In the event that the Examiner is not persuaded as to the patentability of these claims, Applicant requests that specific reasons for the rejection of these claims be given to provide a proper ground of rejection.

F. Claims 6 and 13

With respect to Claims 6 and 13, Applicant submits that neither reference teaches or suggests that the external solenoid and the internal solenoid of the at least one sensor unit are configured to cooperate with the external sensor moving in the 3-D pattern outside the body to generate a detectable coupling signal at a depth of up to at least about 14 cm. Indeed,

Allen primarily describes skull-mounted fiducial markers. Applicant submits that Claims 6 and 13 are patentable over the cited prior art.

G. Claim 42

The Action rejects Claim 42 based on Mate because Mate positions a patient in a registered position and Allen discloses aligning a coupling member to a fiducial marker (citing col. 15, lines 12-52). The Action states that the sensor on the tip of the robot aligns the fiducial marker by touching it. The Action concludes that the sensor on the tip has to use electrical measurement of the coupling signal strength "to find the fiducial marker." Applicant disagrees. The contact finds the marker, and in any event this is not used to define/correlate signal strength to an initial spatial position. The Action then states that the sensor unit is the fiducial marker and the sensor on the tip aligns the sensor unit in three dimensional spaces. Applicant again disagrees. Mate teaches away from the claimed subject matter and one of skill in the art would not have modified the references in the manner alleged to yield the claimed subject matter absent the teachings of the pending application.

Claim 42 is restated below for ease of discussion.

> 42. A method according to Claim 23, further comprising, prior to the moving step:
>
> positioning the patient in an imaging system in a registered position;
>
> obtaining an image of the target treatment site and at least one implanted sensor with the patient in the registered position in an imaging system;
>
> aligning the coupling member to a fiducial marker associated with the imaging system relative to the registered position; and
>
> obtaining an electrical measurement of signal strength of the coupling signal while the patient is in the registered position and the coupling member is aligned and held above the patient to define an initial spatial position correlated to signal strength of the at least one sensor unit in three-dimensional space.

Mate has an integrated registration system with a fixed sensor array 34. There is no need to identify the position of the external solenoid/coupling member prior to active

tracking. Allen requires contact of the fiducial marker, which does not define an initial spatial position for reference with respect to signal strength of the coupling signal as the coupling signal is tracked. Applicant submits that Claim 42 is patentable over the cited prior art for at least the emphasized features and reasons discussed above.

H. Claims 34, 43-45 and 54-57

The deficiencies of the rejections with respect to these claims are discussed above with respect to the corresponding system claims (and independent Claim 34 was discussed with respect to the other independent claims above). The Action rejects these claims based on Mate and alleges that Mate discloses guiding radiation (para. 9, 36) *and transmitting radiation dose using the implanted sensor*. Action, pp. 5-6. Applicant respectfully disagrees. Mate proposes measuring signal strength to determine the location of the markers (para. 36) and guiding radiation therapy (para. 9). However, Mate clearly fails to teach or suggest that the markers 30 can be internal radiation sensors. Thus, Mate fails to teach or suggest the subject matter of Claims 43, 44 and 54.

I. Claims 4, 8-9, 11-12, 19, 46-47 and 52

Claims 4, 8-9, 11-12, 19, 46-47 and 52 stand rejected as being obvious over Mate and Allen in further view of Knapp. The Action concedes that even combined as alleged Mate and Allen fail to teach, *inter alia*, implanted sensors that detect radiation. However, the Action cites Knapp for this subject matter. First, Applicant submits that Knapp fails to resolve the deficiencies of the Mate and Allen as discussed above.

Further, Applicant respectfully submits that a combination of marker and sensor (radiation-Claim 11; temperature-Claims 12 and 46; temperature and radiation-Claim 19; and an internal parameter-Claim 47) configured to operate as claimed is non-obvious over the cited prior art. Applicant agrees that implantable radiation sensors are known. *See, e.g.*, U.S. Patent No. 6,402,689. However, it is the claimed <u>combination</u> of features that is the proper focus of review of patentability. If one of skill were to combine the cited prior art, Applicant submits that they would merely modify the markers of Mate as Mate has an

integrated registration system. There is simply no motivation to modify Mate to use the articulating arm and claimed 3-D pattern coupling signal absent the teachings of the instant application.

CONCLUSION

Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

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